

Study protocol

Investigating an intervention program to reduce suicidal behavior in adolescents with psychiatric disorders: A protocol design



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ABSTRACT

Introduction: Suicide is the leading cause of unnatural death in adolescents. In addition, between 7 and 17% of adolescents may engage in at least one suicide attempt, with prevalence being dramatically higher in adolescents with psychiatric pathology. Death by suicide is usually preceded by several attempts to take one's own life. Among the risk factors most consistently associated with suicidal intent is suicidal ideation. This study aims to evaluate the efficacy of the Self-Awareness of Mental Health (SAM) program enriching standard care, for adolescents at high suicide risk (mental disorder and high suicidal ideation).

Methodology: A randomized single-blind controlled clinical trial will be conducted with a sample of 116 adolescents with suicidal ideation and/or suicide attempt, referred by their psychiatrists from the Hospital Clínico San Carlos (Madrid, Spain). The cohort will be divided into two groups (an intervention group, in which the SAM intervention will be administered as an adjuvant to standard treatment; and a treatment-as-usual group). An extensive clinical assessment on risk factors for suicidal behavior and psychiatric symptoms will be applied up to four times: baseline, post (5 weeks), 3 and 6 months.

Results: Data collection is ongoing. This study will provide data on the effectiveness of the SAM intervention in reducing ideation, preventing the occurrence of suicide attempts, and mitigating emotional symptomatology, such as for anxiety and depression.

Introduction

Suicide is the second leading cause of external death in Spain, leaving 4116 deaths in Spain in 2023,¹ with 555 people between the ages of 15 and 35. In this same age range, in 2019,² suicide was the fourth leading cause of external death in the United States, ranking behind road traffic accidents, tuberculosis and interpersonal violence.³ A large proportion of these deaths could be prevented by improving health services and education. For every suicide death, there are multiple prior attempts to take one's own life.^{4,5} The prevalence of suicide attempts in the adolescent population is estimated to be between 7 and

17% in the general population.^{6,7} This prevalence increases in adolescents with psychiatric pathology,⁸ like affective disorders and substance abuse disorders, with a prevalence of 54%.

It is observed that people who have made a suicide attempt have a higher probability of engaging in a second (or more) attempt and that this one is more lethal than the previous one.^{9,10} In addition, each non-suicidal self-harm attempt may result from the interaction of multiple factors.¹¹ The risk factor most consistently associated with suicidal intent (apart from a previous attempt) is suicidal ideation. Adolescence is a life stage in which suicidal ideation often appears with high intensity among people with mental disorder,^{12,13} especially in individuals with

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major depressive disorder but also with eating disorders, psychotic disorder or impulse control disorder.¹⁴ Psychiatric comorbidity also accounts for higher severity of suicidal ideation and attempts¹⁵ and an increased risk of suicidal behavior.¹⁶

In this regard, multiple factors are strongly linked to non suicidal self-harm and attempts, such as attachment dysfunctions,^{17,18} with Borderline Personality Disorder features,^{19,20} and history of either sexual or physical abuse.²¹ From a dimensional point of view, transdiagnostic factors such as the experience of traumatic or highly stressful situations (e.g., bullying, child maltreatment), deficits in emotional regulation (e.g., presence of non suicidal self-harm, impulsivity, dysregulation in eating patterns), low tolerance of negative emotions or deficits in problem solving in everyday life, have been commonly associated with high ideation, presence of non suicidal self-harm, increased risk of suicide attempt.^{22,23} Some studies point to an increase in suicidal behaviour in the COVID-19 pandemic,^{24,25} showing an increase in symptomatological factors (anxious-depressive symptoms) and emotional dysregulation (eating dysregulation and impulsivity), with a substantial increase in hospital attendances for suicidal behaviour in adolescents.

The World Health Organization² has released the LIVE LIFE guide which addresses measures to develop mental health and bullying prevention programs, support links and protocols for teachers and school and university management to put into practice as soon as a suicide risk is detected. This guide is premised on the premise that suicide deaths among adolescents can be prevented by improving the provision of social and community services, while promoting interventions to prevent suicide attempts. Such interventions should aim to promote physical, emotional and/or behavioral safety in young people's internal and external environments. Studies indicate that early assessment and treatment of adolescents are important in reducing current and future suicidal behavior.²⁶ Therefore, interventions developed to reduce high suicidal ideation would lead to promising results. In this regard, multiple preventive interventions have been proposed with the aim of preventing suicide attempts or reattempts in adolescents. For example, McCauley et al.²⁷ applied a dialectical behavioral therapy-based intervention for emotional regulation in adolescents who had high suicidal ideation and at least one suicide attempt in their lifetime. The intervention program lasted six months. The intervention resulted in a gain in therapeutic change (non suicidal self-harming behavior and/or suicide attempt) of 25% extra at six months of intervention, as well as less depressive symptomatology. Asarnow et al.²⁸ applied a 12-session intervention (one per week) aimed at promoting problem-solving and coping skills to adolescents who had committed a suicide attempt in the last three months and had high ideation. As results, the authors observed that only 6% of the participants included in the treatment committed a suicidal event at six months.

There are other programs applied in general population settings that could be successfully applied for the prevention of suicidal behavior in adolescents with psychiatric disorder.¹³ One intervention that has been found to be efficacious is the Young Awareness of Mental Health (YAM). This universal, school-based mental health promotion primary prevention intervention for adolescents has been translated and adapted to different countries, including Spain. It is framed in the Saving and Empowering Young Lives in Europe (SEYLE) project.^{29,30,31} This program has shown a halving of the risk of suicidal behavior in students aged 13–17 years at one-year follow-up, as well as emotional symptomatology.¹³ Based on YAM, an individual tertiary prevention intervention was developed, the Self-Awareness of Mental Health (SAM). It focuses primarily on providing information in order to increase awareness of mental health and suicidal crisis, learning about risk and protective factors for suicidal behavior, as well as developing problem-solving and coping abilities, including deactivation techniques and assertive communication skills. This brief psychological treatment is intended to empower teenagers who already face stressful life events and have been experiencing suicidal thoughts and/or

self-harm behaviors.

It is considered imperative to propose therapeutic feasible models that help prevent suicidal behavior in adolescents based on programs that have shown adequate efficacy. Furthermore, considering cost-effectiveness aspects such as application time and easiness of administration is of great importance in order to implement the intervention to highly vulnerable adolescents from disadvantaged contexts.

This study aims to evaluate the effectiveness of the SAM suicide prevention program in adolescents with mental disorders and high suicidal ideation, to reduce suicidal ideation, prevent the occurrence of a suicide attempt and reduce depressive and anxious symptomatology. In addition, it aims to achieve the following specific objectives: 1) To evaluate the effectiveness of the SAM program in reducing suicidal ideation in high-risk adolescents (i.e., those with a mental disorder and high intensity self harm thoughts); 2) To examine the effect of the SAM program in reducing the likelihood of presenting a suicide attempt in high-risk adolescents; 3) To examine the efficacy of the SAM program on anxious and depressive symptomatology in adolescents at high risk of suicidal behavior; 4) To study the influence of risk factors for suicidal behavior (self-injurious behavior, symptoms of eating disorders, feelings of emptiness, history of traumatic events, impulsivity) on the effects of the SAM program on suicidal behavior.

Methodology

Study design

This study is conceptualized as a randomized single-blind, 2-arm controlled trial, to test the effectiveness of a suicide prevention program in conjunction with the treatment usually provided by the public health system for adolescent patients with risk of suicidal behaviour.

Participants

Participants between 12 and 18 years old, with suicidal risk (suicidal ideation and/or a suicide attempt in the last 12 months) will be recruited from Mental Health centers linked to the Hospital Clínico San Carlos (HCSC) in Madrid and from the child and adolescent psychiatry ward of the same hospital. The participants will be referred by psychiatrists from these centers, who will propose to the families the incorporation of the adolescents into the study. Once the families have been informed, the researchers contact them and explain in detail the reason for the study. Subsequently, the family and potential participants will be to give more details about the study and to ask them to provide and sign the informed consent.

Eligibility criteria

Patients and legal guardians in case of minors must provide written, informed consent before any study procedure.

General inclusion criteria

The general inclusion criteria are: 1) Attend a Mental Health Center for psychiatric treatment; 2) Be fluent in Spanish; 3) Between 12 and 18 years of age; 4) A score 3 or more on the Paykel Scale of Suicide (PSS)³² or being referred by a clinical psychiatrists due to detected suicide risk, or having shown at least a suicide attempt in the last 12 months; 5) Provided a written consent signed by their parents or legal guards.

General exclusion criteria

The general exclusion criteria are: 1) Autistic spectrum disorder or diagnosed neurodevelopmental disorder; 2) Severe sensory deficit that impairs reading and hearing; 3) Having presented a suicide attempt in the last 30 days, due to the ultra-high risk to show lethal suicide

reattempt^{33,34}; 4) Being involved in another clinical trial, that may interfere with the objectives of the SAM-PSYC study.

Recruitment and follow up

A psychologist or psychiatrist selects participants within the clinical or community context through a clinical assessment, checking for suicidal behaviour, until the required sample ($N = 116$) is reached. Once the selection criteria have been confirmed, participants will be followed up for 12 months. This screening visit will be scheduled for those patients who are willing to participate in the study. Individuals will not receive any financial compensation for their participation.

Study procedures

Eligible participants will be asked for their consent to participate in the study and fill out the Paykel Suicide Scale. Participants will be randomly assigned to the TAU and intervention groups. The SAM program will be delivered to those assigned to the intervention group after the first assessment and the TAU group after the 6-month follow-up assessment. All the participants will be assessed by an independent evaluator, blinded about the experimental condition, using a full battery of clinical instruments at four time points: baseline (V0), 5 weeks after the baseline assessment, 3 months and 6 months (V3-last visit).

Groups and randomization

Patients will be randomly assigned (1:1 ratio) to one of the independent variable groups: intervention group, which will receive the SAM (Self-Awareness of Mental Health) preventive program at the same time as the usual psychiatric treatment (TAU+SAM condition); or a treatment-as-usual (TAU) group (i.e., the usual psychiatric treatment will be received without the SAM program). The TAU care in the Spanish Community of Madrid is provided following the guidelines from the regional strategy of suicide prevention.³⁵ More concretely, the ARSUIIC program was designed to provide mental health services for individuals with suicide risk. The program comprises hospitalization services and psychiatric care prioritization (i.e., an appointment with a psychiatrist must be arranged within the week after hospital discharge to provide specialized care) for patients who attend health units due to suicide-related behaviour. Results derived from the ARSUIIC application can be consulted elsewhere.³⁶

Assessments regarding clinical improvement will be conducted by a researcher blinded to treatment allocation. Due to the nature of the preventive program neither participants or staff can be blinded to allocation.

The SAM intervention

SAM is a manualized, transdiagnostic intervention that endeavors to provide reliable information to the adolescent about protective and risk factors associated with suicidal behavior. It also aims to introduce a range of skills to enable the adolescent to cope more adaptively to everyday problems, stressful and adverse situations as well as intense emotions. The program consists of five 60-minute sessions per week, in-person format. More details of the preventive program are presented in Pérez et al.³⁷ When the adolescents are receiving treatment, they will be in direct contact with the intervention implementer. The session appointments will be scheduled in close contact with the adolescent and their family, under a flexible approach. In addition, the interventions will always take place in the afternoon, so that it does not influence their school schedule.

In the first session, the adolescent will be provided with an overview of the goals of the intervention program, with the establishment of the therapeutic frame and the explanation of the main parts of the participant handbook. Also, information about the adolescent's specific

problems and personal values will be inquired using the garden metaphor from Acceptance and Commitment Therapy. A Safety Plan will be initiated and will be reviewed throughout the sessions. During the second session, a role playing focused on awareness about decision making and how feelings and emotions influence it will be performed. Same way, the skill of finding a safe soothing place and adolescent own self regulation resources will be addressed. The third session will improve the adolescent's knowledge of the concepts of stress and crisis and their consequences, provide tools to facilitate emotional expression and communication in stressful situations and introduce anxiety coping techniques: distraction or mindfulness exercises, deep breathing and progressive muscle relaxation. The fourth session, will consist of psychoeducation on depression, its symptoms and suicidal ideation, as well as myths and stereotypes about suicide, and how to seek for help. Adolescents will be trained on a problem-solving technique. In this session the bus metaphor³⁸ will be used to help adolescents understand the importance of distancing themselves from their appraising thoughts, accepting them and achieving personal goals. Finally, the fifth session will deal with relapse prevention, recapitulate what has been learnt and agree on follow-up appointments. The rider metaphor will be used to deal with the fear of relapse.

All the SAM implementers will be directly trained by the intervention developers by means of face-to-face sessions and recorded materials. Minimal requirements to be an implementer are psychiatry specialty or a master degree in Clinical Psychology.

Measures

Socio-demographic and clinical data including level of education, marital and employment status, will be collected using an ad-hoc clinical interview. Suicidal ideation and behavior will be assessed with the Columbia Suicide Severity Rating Scale³⁹ (C-SSRS) and the Scale for Suicide Ideation⁴⁰ (SSI). The C-SSRS is a clinician-administered suicidal ideation and behavior rating scale that assesses severity and intensity of suicidal ideation, number of suicidal behaviors, and lethality of suicide attempts at time points and over time points. The C-SSRS has a baseline version to be used at the first assessment point and a "since last visit" version that captures suicidal ideation and behavior since the most recent previous assessment. The researcher will apply the questions of the SSI, to corroborate the real presence of suicidal behavior. The administration of the interviews and the SSI will be carried out by a clinician different from the intervention program applicator (blinded evaluator). On the other hand, the medical record will be used as another measurement tool.

Moreover, some self-report instruments will be applied electronically on their Spanish validated versions. The information in response to the instruments will be stored on a secure Google Drive® server owned by the institution of the principal investigator (Universidad Complutense de Madrid).

- The Paykel Suicide Scale (PSS)³² assesses the present of suicidal ideation and suicide attempt in the last 12 months, using a 5-item dichotomous (Yes/No) items. The scale will be used to screen for adolescents with suicide risk.
- The Patient Health Questionnaire⁴¹ (PHQ-9) that rates the frequency of the depressive symptoms during the last 2 weeks using a scale from 0 (not at all) to 3 (nearly everyday) will be used.
- The Barratt Impulsivity Scale⁴² (BIS-11) is a 30-item questionnaire that measures three aspects of impulsivity: (1) motor impulsiveness, (2) attentional impulsiveness, and (3) non-planned impulsiveness.
- The Childhood Trauma Questionnaire - Short Form⁴³ (CTQ-SF), will be used to collect childhood traumatic experiences retrospectively and across five subscales: sexual abuse, physical abuse, emotional abuse, physical neglect and emotional.

- The Feeling of Emptiness Questionnaire⁴⁴ (CSV) is a self-administered questionnaire measuring chronic feelings of emptiness, consisting of 33 items subdivided into five subcomponents.
- The Strengths and Difficulties Questionnaire⁴⁵ (SDQ) It is a screening instrument for behavioral and emotional problems that assesses social competence by means of 25 items, which have five subscales: (1) Emotional symptoms, (2) Conduct problems, (3) Hyperactivity, (4) Problems with peers and (5) Prosocial behavior.
- The Eating Disorder Inventory⁴⁶ (EDI) It is a self-report instrument used to assess symptoms that commonly accompany Anorexia Nervosa and Bulimia Nervosa, which is composed of 64 items, with eight subscales: (1) inclination towards thinness, (2) bulimia, (3) body image, (4) self-esteem, (5) perfectionism, (6) personal relationships, (7) interoceptive awareness and (8) maturation.
- The Bulimic Investigatory Test Edinburgh⁴⁷ (BITE) It is a self-administered questionnaire to identify symptoms of bulimia, consisting of 33 items, which are divided into two independent dimensions.
- The Difficulties in Emotion Regulation Scale⁴⁸ (DERS) It is a self-administered instrument that assesses difficulties in emotional regulation through 36 items with seven subscales: (1) nonacceptance, (2) goals, (3) impulse, (4) awareness, (5) strategies, (6) strategies and (7) clarity.

Outcome and covariates

The primary outcomes are two: a) Suicide-related behavior, understood as the presence of a suicide attempt in the post-intervention and the 6-month follow-up assessments. This will be measured using official medical records. and b) Suicidal ideation intensity, defined as how severe is the suicidal ideation (i.e., the higher presence of active ideation and with higher suicide intent, the more severe the ideation). Suicidal ideation intensity will be measured using the Columbia Suicide Severity Rating Scale³⁹ (C-SSRS).

In terms of secondary outcomes, the number of suicide behaviors measured by the C-SSRS will be considered as a secondary outcome. The mental health diagnosis will be explored using the MINI International Neuropsychiatric Interview (MINI).⁴⁹ Other secondary outcomes will be collected from the medical records: the number of suicide attempts after the intervention delivery, time between intervention delivery and the first suicide attempt; and severity of suicide attempts. Finally, the following symptom-related, self-reported outcomes will be considered: psychopathology symptoms (emotional symptoms, conduct problems and eating-disorder symptoms), difficulties in emotional regulation.

As relevant covariates, the following self-reported factors will be assessed: impulsivity, the history of child traumatic experiences, the presence of chronic feelings of emptiness. Safety endpoints: all adverse events will be collected up to the study final visit (month 6).

Statistical analysis plan

The present project is structured as a randomized controlled trial in which the independent variable between groups is the application of the SAM program in conjunction with the standard psychiatric treatment or the standard psychiatric care alone (TAU group). The main outcomes are: suicidal ideation, suicide attempt and emotional symptomatology. Other variables to be considered in this study are: gender, age, family structure, non suicidal self-harm, previous suicide episodes, psychiatric pathology, feelings of emptiness, eating disorders and body image.

Descriptive statistics will be used to characterize the sample (mean, standard deviation, median, interquartile range and relative frequency) of socio-demographic and clinical data. The chi-square test (χ^2) for independent samples will be used to test whether participants assigned to the intervention and TAU groups differ on dichotomous or categorical variables. The Student's *t*-test for independent samples will also be used

to study the presence of differences between the groups in relation to the variables assessed.

To test whether the intervention is beneficial to reduce the risk of a suicide attempt after the post-intervention assessment, survival curve analysis was followed using the semi-parametric Kaplan-Meier estimator. The presence of a suicide attempt after the follow-up will be the outcome of interest. Cox regression will be used to study whether socio-demographic and clinical predictors would significantly predict attempt engagement. The Akaike information criterion (AIC) was used to evaluate the contribution of the predictors on the explanation of the dependent variable.

Repeated measures analysis of variance (ANOVA) will be applied to study the effects of treatment on the intervention group (compared to the TAU group) across the assessment time points for each dependent variable: suicidal ideation, number of attempts after the intervention, time between attempts, number of suicidal behaviors and emotional symptoms. Post hoc measures (adjusted using the Bonferroni correction) will be used to compare the outcome between the assessment points. To study the presence of suicide attempts between groups, survival analysis will be applied to determine the probability of committing a suicide attempt between groups using the intervention group as a predictor and considering the socio-demographic and clinical factors as covariates.

For the study of risk factors (feelings of emptiness, history of traumatic events, eating disorder symptoms, impulsivity) and their relationship with the efficacy of SAM treatment in the intervention group participants, correlations will be calculated between change scores (posttest minus pretest; follow-up minus pretest) in suicidal ideation and emotional symptomatology and baseline scores on these factors, using Pearson's correlation coefficient; and Cramer's V statistic for the relationship of risk factors with the occurrence of suicide attempt at follow-up. All analyses consider a significance level of 0.05. The statistical package SPSS, version 24 and R software will be used to conduct the study analyses.

Power analysis

An a priori analysis of the sample size needed to visualize a between-group interaction effect (i.e., reduction of symptoms only in the intervention group) for ideation or symptom-related outcomes will be performed, on repeated-measure (3 assessment points: pre-, post- and 6-month follow-up assessment) analysis of variance ($f = 0.25$, $1-\beta = 0.80$ and $\alpha = 0.05$). As a result, a minimum sample size of 62 participants (31 participants per group) will be required. The analyses were conducted with the software G*Power version 3.1.3 (University of Kiel, Germany). Moreover, a survival analysis (parameters: $1-\beta = 0.80$ and $\alpha = 0.05$) will be planned to study suicide attempt risk between the study groups, considering that 30% of sample would be susceptible to a suicide attempt and controlling for the covariates. As a result, a sample of 96 participants (48 per group) would be required. These analyses were performed with MedCalc® 19.5.1 software (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>). However, we estimate a potential sample attrition of 20%, according with existing studies.^{50,51} Therefore, we plan to recruit 116 participants.

Ethics approval and consent to participate

This project has been designed in accordance with the ethical principles set out in the Declaration of Helsinki and the current legislation in force in relation to the protection of personal data (Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights; and EU Regulation 2016/679 of the European Parliament).

All participants will receive detailed information about the study and sign written informed consent before participating in the research. Both parents or legal guards and the adolescent participants will provide with the signed consent to participant. The Clinical Research Ethics

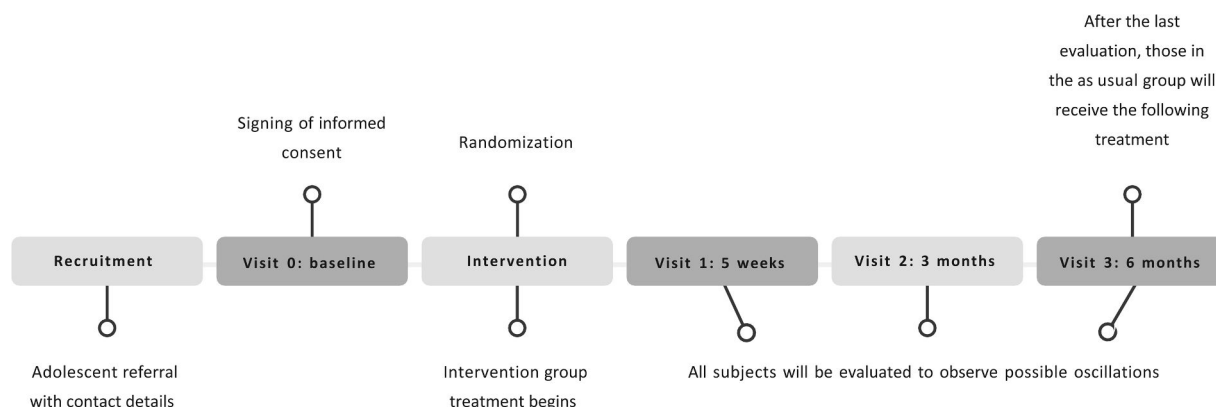


Fig. 1. Study design.

Committee of the Hospital Clínico San Carlos approved the clinical research study (C.I. 21/315-E).

Discussion

This project aims to pave the way for indicated prevention action in health care for adolescents at high risk of suicide, such as those with high suicidal ideation and clinical psychiatric pathology. Suicide is a problem that must be tackled by a modern society that is sensitive to social and health needs. In this sense, suicide is the leading cause of preventable death in the world. In adolescents, it is the leading cause of unnatural death (even ahead of classic events associated with death, such as road traffic accidents). Likewise, the World Health Organization warns on the lack of action in many Western and developed countries, in relation to the development of policies to tackle suicide. Therefore, this project is expected to have a significant scientific, health and social impact. This means, once the results of the project are obtained after the implementation of Self-Awareness of Mental Health treatment, we hope that it will bring about a great improvement in adolescents with regard to the prevention and management of suicidal behavior in health and social centres, which is highly demanded by COVID-19.

On the other hand, the aim is to clarify the relationship between different psychiatric pathologies and the probability of engaging in a suicide attempt. There are severe mental disorders that may cause profound distress. It is hoped that the SAM program will reduce the symptomatology common to varying disorders such as non suicidal self-harm and suicidal symptomatology, depressive and anxious symptomatology. Finally, this project aims to contribute to removing the stigma of people with suicidal behavior. Since people who present suicide attempts or high suicidal ideation are often misunderstood and society agents may attribute their actions to an act of cowardice or an attempt to attract attention, clearly underestimating the degree of suffering. This lack of understanding of the problem of suicide on the part of the different social agents must therefore be confronted with clear and consistent scientific evidence.

Considering the potential threats to achieve the study objectives, it deserves mentioning the chance to have low sample size, which we will try to mitigate by considering different sources from recruited (e.g., visiting mental health centers associated with our health care area and secondary schools to refer adolescents with suicidal behavior). On the other hand, it could be the case of showing more than 20% attrition rate (dropout across assessment points). In this regard, we came from similar studies in the existing literature to estimate the extra recruitment we need to have enough statistical power for analyses. Additionally, protocols to keep adolescents participating are expected to follow (e.g., making reminders through e-mails or telephone calls every month, being flexible for assessment visit appointments to adapt with adolescent's schedule). Finally, the lack of continuity in the SAM program delivery (e.

Table 1
SPIRIT diagram: time and events table SAM-PSYC study.

	Enrolment	Visit 0: baseline	V1: 5 weeks	V2: 3 month	V3: 6 month
Eligibility screen	X				
Informed consent	X				
Assessments (clinician reported)					
Socio – demographic		x			
Columbia Suicide Severity Rating Scale (C-SSRS)		x	x	x	x
MINI International Neuropsychiatric Interview (MINI)		x	x	x	x
Scale for Suicide Ideation (SSI)		x	x	x	x
Assessments (patient self-reported)					
Patient Health Questionnaire-9 (PHQ-9)		x	x	x	x
Barratt Impulsivity Scale-11 (BIS-11)		x	x	x	x
Childhood Trauma Questionnaire – Short Form (CTQ-SF)		x			
Feeling of Emptiness Questionnaire (CSV)		x	x	x	x
Strengths and Difficulties Questionnaire (SDQ)		x	x	x	x
Eating Disorder Inventory (EDI)		x	x	x	x
Bulimic Investigatory Test Edinburgh (BITE)		x	x	x	x
Difficulties in Emotion Regulation Scale (DERS)		x	x	x	x

g., too long interval between sessions) may affect the effectiveness of the program. Flexible schedule will be an option to facilitate the intervention to be delivered within the five consecutive weeks.

Ethics

This protocol and the informed consent forms have been reviewed and approved by the sponsor and the institutional review board (IRB)

and ethical committee (ECs) at Hospital Clínico San Carlos (HCSC).

This project has been designed in accordance with the ethical principles set out in the Declaration of Helsinki and the current legislation in force in relation to the protection of personal data (Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights; and EU Regulation 2016/679 of the European Parliament). The public prosecutor for minors will be informed in relation to the implementation of the study. Finally, the project will consist of an information and informed consent form that will be signed by both participants and parents or legal representatives, consenting to participation (Fig. 1, Table 1).

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Declaration of competing interest

The rest of the authors declare no conflicts of interest.

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